DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

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The Honorable Henry A. Waxman
Ranking Minority Member
Committee on Government Reform
House of Representatives
Washington, D.C. 20515-6143

Dear Mr. Waxman:

Thank you for your letter, co-signed by Representative Elijah E. Cummings, in which you express concern regarding the presentation of scientific evidence on the efficacy of syringe exchange and "harm reduction" programs to prevent the spread of HIV and other blood borne illnesses. I have enclosed a brief response to the areas of interest you identified in your letter.

I hope you find this information useful. If you have further questions or need additional information, please contact Dr. Steve Gust, Interim HIV/AIDS Coordinator at the National Institute on Drug Abuse, at 301-443-6480.

An identical letter is being sent to Mr. Cummings.

Sincerely,

Elias A. Zerhouni, M.D.
Director

Enclosure

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1. Strategies That Have Proven Successful in Reducing The Risk of HIV Infection Among IDUs.

One successful strategy for reducing the risk of HIV among injection drug users (IDUs) is to provide drug abuse treatment. Drug treatment programs provide a good setting for reaching IDUs and their partners with HIV prevention and care messages and interventions. It also can be a bridge to other needed services, such as primary health care, mental health, or other social services.

Numerous studies, primarily focused on methadone maintenance treatment (MMT), have shown that substance abuse treatment programs can have a dramatic effect on HIV transmission among opiate injectors, reducing their risk as much as 4- to 6-fold.[1,2] Drug abuse treatment works principally because it helps IDUs decrease the number of injections or helps them stop injecting altogether. Less use leads to fewer drug-related risk behaviors, and that in turn leads to fewer exposures to HIV. The beneficial effects of MMT are most evident when treatment lasts a sufficiently long time and when methadone doses are high enough to effectively block drug craving: One study showed that 3.5 percent of methadone patients who had been in treatment continuously for 18 months had become infected with HIV, compared to 22 percent of out-of-treatment IDUs;[3] another study showed that at 36 months, 8 percent of IDUs in treatment had become infected,[4] as compared to 30 percent of injectors not in treatment. An analysis of 20 years of social and medical data on 622 MMT patients in New York City showed that those patients who received methadone doses of 80 mg or more were significantly less likely to have HIV infection than patients who received smaller doses.[5] The protective value of higher doses was independent of a number of other risk factors, including year of last cocaine injection, needle sharing in shooting galleries, number of IDU sex partners, income, and race/ethnicity. Moreover, among non-injection cocaine users, drug treatment has also been shown to decrease cocaine use from an average of 10 days per month at baseline to 1 day per month at 6 months. Reduction in cocaine use was associated with an average 40 percent decrease in HIV risk across gender, and ethnic groups, mainly as a result of fewer sexual partners and less unprotected sex.[6]

Drug addiction treatment[7] is an essential component of a comprehensive prevention program to reduce risk of HIV and other blood-borne infections among IDUs. Since the late 1980s, studies have shown that treatment works because drug users in treatment stop or reduce their drug use and related risk behaviors, including use of non-sterile syringes and unsafe sex. Drug treatment programs also serve an important role in providing up-to-date information on HIV/AIDS, hepatitis, and other sexually transmitted diseases (STDs), counseling and testing services for these infections, and referrals for their clients to obtain medical and social services.

However, the majority of those needing treatment are not currently in a treatment program. The NIDA Community-Based Outreach Model[8,9] was designed to reach out-of-treatment IDUs who are unable or unwilling to stop using and injecting drugs and who cannot or will not access drug treatment. Compared to those in treatment, out-of-treatment IDUs are at significantly greater risk of HIV and other infections because they are more likely to inject drugs more frequently, to share drugs, syringes, and other injection equipment, and to practice unsafe sex while under the influence of drugs. The outreach program developed by NIDA attempts to reduce HIV risk through education on the risk factors for HIV transmission and by teaching effective skills in reducing those risks.

The Federal Government has extensively examined the effectiveness of syringe exchange programs (SEPs) dating back to 1993, including reviews by the Government Accountability Office.[10] Several non-governmental organizations, including the American Psychiatric Association, and others have also endorsed the use of SEPs as effective public health interventions. The current scientific literature supports the conclusion that SEPs can be an effective component of a comprehensive community-based HIV prevention effort.

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2. The Role Played by Harm Reduction Programs in Stemming the Spread of HIV in the United States.

3. The Relative Rate of HIV Infection in Cities That Have Implemented Harm Reduction Programs Versus Those That Have Not.

As a public health agency, the goal of the National Institutes of Health (NIH) and specifically the National Institute on Drug Abuse (NIDA) is to improve the quality of the Nation's addiction treatment and prevention, using science as the vehicle. The term 'harm reduction' has various meanings depending upon the context in which it is used, and is not viewed as a scientific term for any particular approach to addressing drug addiction. However, a great deal of research has been conducted on methods of reducing risks to health, such as syringe exchange programs (SEPs).

Research shows that SEPs, when implemented as part of a comprehensive HIV/AIDS prevention strategy, can be an effective public health approach to reduce the spread of HIV and other blood borne pathogens in the community. SEPs reduce the circulation time of contaminated injection equipment and thereby reduce opportunities for reuse of contaminated injection equipment and the transmission of new infections.[1-2] A number of studies conducted in the U.S. have shown that SEPs do not increase drug use among participants or surrounding community members and are associated with reductions in the incidence of HIV, hepatitis B, and hepatitis C in the drug-using population.[3-7]

Hurley, et al.,[8] reviewed published and unpublished reports from 1984 to 1994 on HIV seroprevalence among IDUs in 81 cities across Europe, Asia, and North America with and without SEPs. On average, seroprevalence increased by 5.9 percent per year in the 52 cities without SEPs and decreased by 5.8 percent per year in the 29 cities with SEPs. The average annual change in seroprevalence was 11 percent lower in cities with SEPs. Thus, in cities with SEPs, HIV seroprevalence among IDUs decreased on average, but in cities without SEPs, HIV seroprevalence increased, suggesting that SEPs led to a reduction in HIV incidence among IDUs.

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4. Evidence Comparing HIV Treatment Regimen Compliance Among IV Drug Users vs. Non-IV Drug Users.

HIV-infected drug abusers can achieve positive health outcomes if they have access to and adhere to treatment with antiretroviral drugs (ART). Studies have also demonstrated the importance of ongoing interventions to reduce drug abuse and associated risk behaviors in order to maximize the health benefits of ART. However, there is cause for concern that health outcomes in drug abusers infected with HIV may be inferior to non-drug users. The often chaotic lifestyles of drug abusers combined with their increased likelihood of co-occurring medical and psychiatric conditions can complicate their treatment and prevent their achieving the same health outcomes as non-drug users. Access to medical care is another crucial factor. Individuals who receive HIV treatment later in the course of their disease are more likely to have viral rebound associated with development of resistance to ART than those who receive early treatment.[1] Finally, preclinical or basic research studies indicate that some drugs of abuse affect the immune system, the target of HIV infection, which may also impact vulnerability to infection and course of illness.

Factors associated with treatment compliance in drug abusing populations are discussed below.

Adherence to HIV treatment among drug users

The cumulative research indicates that non-adherence to antiretroviral therapy (ART) occurs in both drug users and non-drug users, reflecting the difficulty of adhering to complex regimens which require high accuracy in dosing schedule and compliance with dietary instructions. Estimates are that about 40 percent of patients receiving ART have significant problems with adherence.[2] A study of adherence among non-drug-using patients found 53.1% reported taking all medication on time according to dietary instructions, i.e., were fully adherent.[3] It is important to recognize that not only do treatment outcomes depend upon adherence to medication regimens, but also the risk of developing resistant HIV strains may be related to the level of sustained treatment adherence.[1]

A number of predictors of poor ART treatment adherence have been demonstrated in research studies. These include illicit drug use, as well as depression, alcohol use, poor self-efficacy, and certain health beliefs. However, the evidence from individual studies is not consistent--in some cases no differences are found between drug users, former drug users and non-drug users, and in other cases clear evidence of poorer adherence and lower HIV viral suppression is found in active drug users. Examples of this research follow:

- In one study, the strongest predictor of poor ART adherence in drug users was active cocaine use (27% in abstinent users vs. 68% in active users). Other factors included female gender, being unmarried, screening positive for depression and use of alcohol.[4]
- In a cohort of HIV infected women adherence was found not to be stable over time, with factors such as active drug/alcohol use, more frequent antiretroviral dosing, younger age, and lower initial CD4 lymphocyte count predicting poor ART adherence.[5]
- Lucas, et al.,[6] identified the effects of substance abuse status on utilization of highly active anti-retroviral therapy (HAART), medication adherence, and virologic and immunologic responses to therapy in a cohort of HIV-1-infected patients attending an urban HIV clinic. Active drug use was strongly associated with underutilization of HAART, non-adherence,

and inferior virologic and immunologic responses to therapy. Former drug users and non-drug users were similar in all outcomes.

- Another study by this group[7] indicated that switching from non-use to substance abuse was strongly associated with worsening ART use and adherence, and less frequent HIV-1 RNA suppression, compared to remaining free of substance abuse. Conversely, switching from substance abuse to non-use was strongly associated with improvements in ART use, adherence and treatment outcomes.
- Not all studies support an association between drug abusers and poor adherence. A study of factors relating to adherence to antiretroviral therapy among pregnant women indicated that adherence to antiretroviral therapy was not significantly associated with use of illicit drugs. Analyses were based on pharmacy claims data in a sample of 549 HIV-infected women who were prescribed antiretroviral therapy and who delivered live infants.[8]

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5. The Use of Harm Reduction Strategies in Areas Other Than HIV and Drugs, Such as Speed Limits, Seat-Belt Laws, Minimum Age of Alcohol Consumption, and Public Education and Peer Outreach Concerning Smoking.

The reduction of risk for injury and death has been the focus of research in a number of fields. In traffic safety, reduced speed limits[1] and seat-belt laws[2] have reduced the likelihood of crashes and the severity of injuries sustained in those crashes. The Insurance Institute for Highway Safety has published a selection of findings on the prevention and consequences of increased speed limits in several editions of *Status Report* including, "Seven straight years: deaths higher after 65 mph speed limits than before" in 1994 and "Faster travel and the price we pay" in 2003. More information is available on the Insurance Institute for Highway Safety's website at http://www.highwaysafety.org. The Centers for Disease Control and Prevention's (CDC) National Center for Injury Prevention and Control houses a Task Force on Community Preventive Services which has published findings on seat-belt use interventions and the effectiveness of safety belt use laws. CDC's reports have been featured in publications including numerous issues of the *Morbidity and Mortality Weekly Report* (MMWR) and Volume 21 of the *American Journal of Preventive Medicine* (AJPM).[3] More information is available on the National Center for Injury Prevention and Control's website at http://www.cdc.gov/ncipc/.

Research in the alcohol field has shown that crashes and injuries have been reduced by raising the drinking age,[4,5] reducing the allowable blood alcohol concentration (BAC) for drivers,[6] and enacting zero tolerance laws for younger drivers.[7,8] Research has also shown that providing a brief intervention to reduce a person's drinking lowers the probability of making a subsequent visit to an emergency room.[9]

Education aimed at better informing the public on smoking and health issues are an important part of tobacco control and prevention efforts.[10] It is vital that the public understand that, to date, the only proven way to reduce the enormous burden of disease and death due to tobacco use is to prevent youth from beginning to smoke, and to help smokers, both youth and adults to quit.[11] Today, we have much to offer people who smoke and want to quit, including effective behavioral treatments and medications.[12] The evidence strongly suggests that people who keep trying to quit do succeed, although many will require numerous attempts before being successful.[13]

Recently, a number of new tobacco products with claims purported to reduce health risk have entered the market.[14-16] Unlike smoking cessation products, tobacco products do not undergo rigorous, objective scrutiny either for their constituents or for the accuracy of their health claims. A greater science base is required before we will know what effect these new products will have on the health of the public.[17-19]

To be effective, education, and outreach efforts must take into account the knowledge, attitudes, and behaviors – among other factors – of the intended audience.[20] To understand these and related issues, the National Cancer Institute (NCI) has developed and implemented the Health Information National Trends Survey (HINTS), which collects nationally representative data about the American public's use of cancer-related information and perception of cancer risks. HINTS contains questions about tobacco product use, including tobacco products purported to reduce health risk. These data will be useful to help shape future public education efforts.[21]

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